United States Court of Appeals

for the Second Circuit

APPELLANT'S BRIEF

To be Argued by
COPAL MINTZ

74-1999

B
P/C

No. 74-1999

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation,

Defendant-Appellant.

On Appeal from the United States District Court for the Eastern District of New York

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Defendant appeals from a judgment of "Permanent Injunction" of the United States District Court for the Eastern District of New York (John F. Dooling, Jr., J.) entered July 18, 1974, which, presumably, supersedes a final judgment of "Permanent Injunction" of the same Court (by the late Rosling, J.) entered two years pre-

viously, on July 18, 1972, which was affirmed by this Court (485 F 2d 677) and certiorari of which was denied by the Supreme Court (94 S.C.1938,4/15/74).

The July 18, 1974 judgment is far more drastic and extensive than the judgment of July 18, 1972. The latter had reserved to the Court jurisdiction "for the purpose of enforcing or modifying this Permanent Injunction; and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate".

THE ISSUES

Manifestly, the issues on this appeal are:

1. Did the Court have power to enter a new judgment containing <u>additional and different</u> restraints, impositions and requirements?
2. Did the Court have power to do so in the absence of evidence and findings of vital changes of circumstances?
3. Assuming some modicum of power, was there new evidence and are there new findings which justify the alterations and importations of the new judgment?
4. Are the new provisions authorized by or reconcilable with the Federal Food, Drug and Cosmetic Act?

Appellant contends that the answer to each of those questions is no.

THE CASE

This action was commenced in 1968. It was tried between June 1971 and February 10, 1972. A decision of 41 pages followed on June 9, 1972, which incoporated by reference earlier interlocutory findings and conclusions set forth in writings aggregating over 80 pages. A final judgment of "Permanent Injunction", dated July 15, 1972 was filed July 18, 1972. That judgment was affirmed by this Court on October 24, 1973 (485 F 2d 677). On April 15, 1974, the Supreme Court denied a petition for certiorari (94 S.C.1938).

On August 1, 1973, the plaintiff instituted a criminal contempt proceeding against the defendant and two of its officers, charging that they violated the injunction of July 18, 1972 in a number of respects and the preliminary injunction in one respect - all between July 19, 1972 and September 25, 1972 (65A-67A, 76A-83A, 85A-86A)*. That contempt proceeding was

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* Numerals followed by the letter A refer to pages of the Appendix bearing those numbers.

tried before Judge John F. Dooling, Jr. and a jury on April 8 through April 12, 1974 and was dismissed at the end of the Government's case (93A-95A).

Nowhere is there a claim or suggestion of any conduct after September 1972 on the part of the defendant or its personnel inconsistent with scrupulous observance of the injunction.

Judge Dooling, however, expressed the view that the terms of the judgment should be clarified to make its terms more definite and certain so as to eliminate a repetition of controversy as to the meaning of the injunctive provisions. Upon consent of the parties, further hearings were held on April 15 through 18 and on April 22. After receiving memoranda from the parties, Judge Dooling, on May 7, 1974, filed a 39-page "Memorandum Incorporating Findings of Fact and Order" (65A-102A).

That order directed that "proposed modifying paragraphs" [modifying the July 1972 judgment] "within limits indicated by the sense" of his decision, "be settled on notice" (99A). The parties submitted radically different proposed judgments - the plaintiff a 12 page document (104A), the defendant a 5 page proposal.

There eventuated the 13 page "Permanent Injunction" which is the subject of this appeal (125A-138A, 141A).

Significant Differences Between the Two Judgments

1. The 1972 3 1/2 page judgment (61A-63A) related exclusively to the labeling or branding of a device described as "an electromagnetic generator similar to conventional medical diathermy but differing from it in that its output is pulsed and in that it lacks the energy output of conventional medical diathermy" (61A) and "permanently enjoined" the defendant and its officers, etc. "from violating 21 U.S.C. 331(a) and (k) by directly or indirectly" "causing to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce, or otherwise disposed of", any such device, "in whole or in part, assembled or unassembled, unless and until the said defendant assembles the scientific evidence on which labeling of the device is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106, and the defendant submits such evidence and labeling to the Food and Drug Administration and obtains approval thereof in writing" (61A-63A).

The 1974 judgment (125A-138A) extends the prohibitions to, and includes therein, devices with all the energy output of conventional medical diathermy and prohibits the defendant from interstate shipping of such devices "both in whole or in part, whether assembled or unassembled and components, parts, accessories, assemblies and subassemblies, usable or adaptable to create defined devices or to convert other devices into defined devices" (at 126A-128A) "unless and until the said defendant assembles adequate scientific evidence on which labeling of said prohibited devices is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106(d), and the defendant submits such evidence and such proposed labeling to the Food and Drug Administration, Rockville, Maryland, and obtains approval thereof in writing: ..." (at 130A).

It does so by specially and broadly defining the terms "devices" (Section II(B) at 126A), by adopting and defining a term "prohibited device" to include any device which has such capabilities (Section II(E) at 126A-127A) and by Sections III and IV (at 127A-135A)

which contain the conditions precedent just quoted. In contrast, all other manufacturers and distributees freely market interstate conventional diathermy devices whether or not and regardless of how pulsed with standard extensive therapeutic claims (see 107A-112A, 114A-119A, 122A-124A).

2. The 1974 judgment innovately incorporates a provision not contained in the 1972 judgment, reading: "any of such prohibited devices in the possession of any practitioner licensed by law to use or order the use of any of said prohibited devices shall be deemed to be held for sale" (Section III(B) at 129A). Thereby the Court has amended the statute to extend FDA's and the Court's authority and jurisdiction (see infra pp.43-4.

3. The 1974 judgment, unlike the 1972 judgment, mandates that the defendant shall "cause the prohibited devices of Section II(E)(2) heretofore introduced or delivered for introduction into interstate commerce and all labeling accompanying said prohibited devices ... to be returned to the possession of the defendant ... at defendant's expense" and that defendant prepare and

deliver to FDA lists of the devices thus returned, of the"devices unavailable to be returned" together with the reason for [their] unavailability" and of the "returned labeling" (Section IV(D)(1) and (2) at 133A-134A; emphasis added).

4. The 1974 judgment, unlike the 1972 judgment, requires the defendant: to "determine whether to attempt to bring the said returned devices into compliance with the law by relabeling or modification" if and as approved by the FDA, or "whether to destroy or salvage (for other than device purposes) the said returned devices"; to notify FDA of its election; and "not commence such destruction or salvaging operations until it [defendant] has received authorization in writing to do so from" the FDA (Section IV(D)(3)(a) at 134A).

Moreover, the 1974 judgment adds: "the defendant shall under no circumstances whatsoever ship, sell, offer for sale, or otherwise dispose of any part of said returned devices until duly authorized representatives of the Food and Drug Administration shall have had free access thereto in order to make any examination or inspections that are deemed necessary, and shall in writ-

ing have released said devices for shipment, sale or other disposition" (Section IV(D)(3)(b) at 134A-135A).

5. The 1974 judgment, unlike the 1972 judgment, requires the defendant to inform FDA of the location of each of the offices, plants, factories, warehouses, storage facilities, or other establishments used by the said defendant for the manufacturing, assembling, processing, packing, transporting, or holding of any device or which is used by the said defendant to hold any equipment, finished and unfinished materials, containers, labeling, records, files or other papers bearing on the manufacturing, assembling, processing, packing, transporting, or holding of any devices; and shall thereafter submit notice in writing to the Food and Drug Administration, Rockville, Maryland, as to each disposition or acquisition of such establishments within 10 days of each such occurrence" (Section V(A) at 135A).

6. The 1974 judgment, unlike the 1972 judgment, mandates the defendant also to grant FDA "free access" to any of its establishments "at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all

pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in place." (Section V(B) at 135A-136A).

7. The 1972 judgment directed the defendant, within 30 days, to send a copy of the judgment "to each and every person known to the defendant to have purchased, leased or have in his possession a Diapulse device" and also to other categories of persons therein specified and to "advise plaintiff of the name and address of every person so notified" (63A-64A).

Although that was done, (see 99A),

the 1974 judgment requires the defendant, within 30 days of the entry of the judgment, to submit to FDA a form of notice to accompany a copy of the 1974 judgment and within 30 days after FDA's approval of such a notice to send a copy thereof together with a copy of the 1974 judgment to each of the same persons and to "advise in writing the United States Attorney ... of the name and addresses of each such person so notified" (Section VI at 136A-137A).

The Sole Clarification

The sole digression from the 1972 judgment which may be at all helpful to the defendant is a provision which expressly excludes from the prohibitions of the judgment "shipment or other delivery for investigational or research purposes" (Section IV(C) at 131A-132A). But even that is circumscribed by the requirement of advance submissions to the FDA of minutely detailed information of the proposed investigation or research project and of by whom (with all their professional qualifications), where, when, how, and how long the project will be conducted and that periodic and final reports be furnished to FDA. There is the further provision that if the FDA disapproves, the "plaintiff may apply at the foot of this injunction (pursuant to Section VII) for an order specifically extending the prohibitions of this injunction to such shipment or delivery" (131A-132A).

The Common Provision in Both Judgments

The 1974 judgment, like the 1972 judgment, retains jurisdiction in the court "for the purpose of enforcing or modifying this Permanent Injunction, and for

the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate" (64A, 137A).

The Effects of the Changes and Additions

1. As indicated at pages 5-7 supra, the effect of Sections II-IV of the 1974 judgment (at 125A-131A) is to add to the prohibition of the marketing of Diapulse or any other athermal modality unless and until the labeling thereof is approved by the FDA, like prohibition of modalities which have all of the thermal capabilities of so-called conventional diathermy. Thereby the defendant is prohibited from marketing interstate a device which freely is marketed by a substantial number of concerns without clearance or approval and without hindrance by the FDA and without requiring from any of them "adequate scientific evidence" in support of their numerous standard therapeutic claims (107A-112A).

That is accomplished by expanding the injunction to any device unless it

> "is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects from

a core body temperature of 98.6° F to 104°F in 20 minutes or less at a majority of its operational settings; and (3) the said device is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects to a range of temperatures of 104°F to 113°F at a series of readily selected settings of the said device (Section II(E)(3) at 127A).

2. The effect of Section III(B), at 120A, is pointed out at page 7 supra.

3. The provision that defendant shall "cause" the return to the defendant, at its expense, of all Diapulses heretofore shipped interstate [during the past 15 years or so], by whomsoever and wheresoever now owned or held - some 4,000 or so (see 67A). obviously imposes upon the defendant a tremendous expense including the maintenance of extensive storage facilities. These are to be converted, if FDA approves, or destroyed. At whose expense such conversion is to be accomplished is not specified. What liability defendant will incur by failing to convert is not spelled out. Surely, an avalanche of litigation is likely to follow.

4. The "free access" provisions, noted at pages 9-10 supra, deny the defendant the protection

against, and immunity from, "unreasonable searches and seizures" of the Fourth Amendment to the Constitution of the United States. It also disregards the limitations which Congress so carefully put into Section 374 of the Food, Drug and Cosmetic Act (see infra pp. 45-50).

5. The provision for mailing of notice (approved by the FDA) and a copy of the judgment "to each person known to the defendant to have purchased or leased, or to have in his possession, any of said prohibited devices", within 30 days after receipt of FDA's approval of the notice and to furnish lists of those to whom the notice and judgment are mailed (Section VI, at 136A) imposes still an additional burden on the defendant.

PREVIOUS DECISIONS

This case was before this Court in 457 F 2d 25 (1972) and in 485 F 2d 677 (1973) Cert. denied 94 S.C.1938, 4/15/74.

A related seizure case was before this Court in 389 F 2d 612 (1968), Cert. denied 392 U.S. 907.

Somewhat related other cases which have been passed on by this Court are Diapulse Corporation of

America v. The Bircher Corp., 362 F 2d 736 (1966), pet. for cert. dismissed 385 U.S. 801; and Diapulse Corporation of America v. Federal Food and Drug Administration, F 2d , 5/9/74.

THE PERTINENT STATUTES AND RULES

Amendment of, and relief from, judgments or orders are provided for in FRCP 50(b), 52(b), 59 and 60.

Rule 50(b) entitled "Motion for Judgment Notwithstanding the Verdict" has no relevance to this appeal other than furnishing a contrast to Rule 60(b). A motion thereunder must be made "Not later than 10 days after entry of judgment". The moving party

> "may move to have the verdict and judgment entered thereon set aside and to have judgment entered in accordance with his motion for a directed verdict. ... the court may allow the judgment to stand or may reopen the judgment and either order a new trial or direct the entry of judgment as if the requested verdict had been directed."

Additional ancillary powers are set forth in section (c).

Rule 52(b) provides, so far as relevant to the consideration of this case:

"(b) Amendment. Upon motion of a party made not later than 10 days after entry of judgment the court may amend its findings or make additional findings and may amend the judgment accordingly. ..."

Rule 59, entitled "New Trials; Amendment of Judgments" provides, in part, as follows:

"(a) Grounds. A new trial may be granted to all or any of the parties and on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States; and (2) in an action tried without a jury, for any of the reasons for which rehearings have heretofore been granted in suits in equity in the courts of the United States. On a motion for a new trial in an action tried without a jury, the court may open the judgment if one has been entered, take additional testimony, amend findings of fact and conclusions of law or make new findings and conclusions, and direct the entry of a new judgment. [Emphasis added]

* * * * *

(d) On initiative of Court. Not later than 10 days after entry of judgment the court of its own initiative may order a new trial for any reason for which it might have granted a new trial on motion of a party. After giving the parties notice and an opportunity to be heard on the matter, the court may grant a motion for a new trial, timely served, for a reason not stated in the motion. In either case, the court shall specifyin the order the grounds therefor. [Emphasis added]

(e) Motion to Alter or Amend a Judgment. A motion to alter or amend the judgment shall be served not later than 10 days after entry of the judgment." [Emphasis added]

Rule 60, in its entirety, provides as follows:

"Relief from Judgment or Order

(a) Clerical Mistakes. Clerical mistakes in judgments, orders or other parts of the record and errors therein arising from oversight or omission may be corrected by the court at any time of its own initiative or on the motion of any party and after such notice, if any, as the court orders. During the pendency of an appeal, such mistakes may be so corrected before the appeal is docketed in the appellate court, and thereafter while the appeal is pending may be so corrected with leave of the appellate court.

(b) Mistakes, Inadvertence; Excusable Neglect; Newly Discovered Evidence; Fraud, etc. On motion and upon such terms as are just, the court may relieve a party or his legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application;

or (6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken. A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court to entertain an independent action to relieve a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C. § 1655, or to set aside a judgment for fraud upon the court. Writs of coram nobis, coram vobis, audita querela, and bills of review and bills in the nature of a bill of review, are abolished, and the procedure for obtaining any relief from a judgment shall be by motion as prescribed in these rules or by an independent action." [Emphasis added]

Substantively, the 1974, as the 1972, judgment is under and purportedly in enforcement of the Food, Drug and Cosmetic Act (Title 21 of the U.S. Code). The following provisions of that Act are pertinent:

"§ 321 Definitions; generally. For the purposes of this chapter

* * * * *

(h) The term 'device' (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other

animals; or (2) to affect the structure or any function of the body of man or other animals."

"§331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.

* * * * *

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

"§332. Injunction Proceedings - Jurisdiction of courts.

(a) The district courts of the United States and the U.S. courts of the territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (h)-(j) of said section."

"§334. Seizure - Grounds and jurisdiction.

* * * * *

(d) (1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: ..."

"§352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded

(a) If its labeling is false or misleading in any particular.

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; ..."

"§374. Inspection - Right of agents to enter; scope of inspection; notice; promptness; exclusions. [Reproduced at pages 48-50 infra]

Pertinent also is the following provision in 21 CFR:

"1.106 Drugs and devices; directions for use

* * * * *

(d)

* * * * *

(3) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer

the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertized or represented: Provided, however, that such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. ..."

ARGUMENT

I

THE DISTRICT COURTS, AFTER THE PASSING OF THE 10 DAY AND 20 DAY PERIODS PROVIDED IN FRCP 50, 52 and 59, ARE WITHOUT POWER TO ALTER FINAL JUDGMENTS (EXCEPT TO CORRECT CLERICAL MISTAKES) OTHER THAN TO VACATE THEM, IN WHOLE OR IN PART.

(1) Verbal Connotation

As appears at pages 15-18 supra, Rule 60, as amended in 1946, is the only rule which deals with amendment of final judgments after the expiration of the 10 and 20 day periods provided for in Rules 50, 52 and 59.

It is noteworthy that Rules 50, 52 and 59, notably the latter, say that the courts may "open the judgment ..., take additional testimony, amend

findings of fact and conclusions of law or make new findings and conclusions, and direct the entry of a new judgment", and Rule 60(a), in referring to "clericle errors", uses the words "may be corrected" (emphasis added]. In marked contrast, Rule 60(b) does not contain, in any form, the verbs "amend", "alter", "make new findings and conclusions", "direct the entry of a new judgment".

Rule 60 is captioned "Relief from judgment or order" [emphasis added]. Subdivision (a) thereof relates only to "clerical errors"; it provides that they "may be corrected" and stipulates no time limitations.

Subdivision (b), however, concerned with substantive changes, very restrictively provides:

> "On motion and upon such terms as are just, the Court may relieve a party or his legal representative from a final judgment, order or proceeding for the following reasons: ...".

We all know that "relieve from" does not mean also "add to", just as we know that subtract does not mean also add. There is no ambiguity in the meaning of the phrase "relieve from". The dic-

tionaries define "relieve" to mean "to free from a burden ... to bring about ... removal or alleviation ..., make less burdensome or afflicting, mitigate, lessen, alleviate ... to set free from an obligation, condition or restriction ... to ease of an imposition, burden, wrong, or oppression by judicial or legislative interposition ..." (Webster's Third New International Dictionary - Unabridged); "to ease; lighten, reduce, ... to free ... to set free from a burden, obligation" (Webster's New World Dictionary).

As synonyms, Webster's New International lists "alleviate, lighten, assuage, mitigate, allay".

(2) Historical Context

Were the authors of the 1946 reformulation of Rule 60(b) careless or unmindful of the meaning of "relieve from"? What was their intent?

Moore's Federal Practice, in Volume 7 of the Second Edition, answers that in over 300 pages devoted to the history of the 1946 amendments, the reasons therefor, the purposes thereof and their effect in the light of their legal lineage. The following brief synopsis may be helpful.

The common law and equity remedies which were available prior to the Federal Rules "afforded substantial relief from judgments at law and in equity in certain limited situations" (pp. 75-6; emphasis added). Original Rule 60(b), in effect and as construed, preserved the substance of those complex ancient remedies inherited from English law (pp. 77-91) and "shrouded in ancient lore and mystery (p. 208). Thus construing the Rule as preserving the substance of the old remedies in a new procedure, the courts applied those remedies to the extent and in the circumstances that relief was awardable under their common law and equity powers before 1939 (pp. 77-81; Wallace v. United States, 142 F 2d 240, 242-5, 2d Cir. 1944). The effect was "merely to recognize a power already existing; not to create or to enlarge the old ones" (Fraser v. Doing, 130 F 2d 617, 622, C.A.D.C. 1942).

As thus construed and applied, original 60(b) "operated reasonably well" (p. 91). However, because it lacked exclusivity, it "was most deficient" (p. 91), and after several years of intense research and delib-

eration by the Advisory Committee, present Rule 60(b) was evolved and came into effect in 1946 (pp.201-10). The Committee concluded - it deemed it "obvious that the rules should be complete ... and define the practice with respect to any existing rights or remedies to obtain relief from final judgments" (p. 207, quoting from the Committee's 1945 Note); hence, should be amended to "permit, either by motion or by independent action, the granting of various kinds of relief from judgments which were permitted in the federal courts prior to the adoption of these rules" (p. 201, quoting from the Advisory Committee's 1946 Note). Moore's concludes:

> "It is fair to say that amended 60(b) evolved slowly; that it is the product of careful study on the part of the Committee; and that it is a deliberate balancing of the competing principles of finality and relief from unjust judgments" (p. 203).

At pages 340-341 Moore's says:

> " ... Rule 60(b) states the basis for relief from a judgment; and thus operates both as a grant and limitation upon power of the district court to give relief from a final judgment [Emphasis added].
>
> The revision of the Rules in 1946 had, among other objectives, achievement and balancing of two general purposes that are,

at least in part, competing and conflicting: (1) to buttress the finality of judgments; and (2) to provide ample and proper grounds for relief from final judgments. Relative to the second purpose, Rule 60 was amended extensively to clarify the former practice and to state clearly the reasons for relief from final judgments and time within which particular reasons must be urged. The reasons stated in clauses (1)-(5) are the traditional and common grounds for relief. ... But some general residual clause is necessary to cover unforeseen contingencies even at the risk of undercutting the principle of inclusiveness at which amended 60(b) was generally aimed. [Footnote references omitted]

Clause (6) is the residual clause. After enumerating 5 rather specific reasons for relief, Rule 60(b) also authorizes the district court, in the exercise of a sound discretion, to relieve a party or his legal representative from a final judgment, order or proceedi for

'(6) any other reason justifying relief from th operation of the judgment.'

The only time limitation upon relief under clause (6) is one of 'reasonable time'. [Emphasis added; footnote references omitted]

As we have seen one purpose of the 1946 revision was to incorporate generally the substance of the old common law and equitable ancillary remedies into amended 60(b). And to the extent that precedent dealing with these old remedies would warrant relief in a situation not covered by clauses (1)-(5), then that precedent is persuasive for the grant of relief under residual clause (6) ..."

At page 342, Moore's quotes, in regard to reason (6), from Judge Black's opinion in Klapprot v.

United States, 335 U.S. 601, 614-615 (1949):

> "In simple English, the language of the 'other reason' clause, for reasons except the five particularly specified, vests power in courts adequate to enable them to vacate judgments whenever such action is appropriate to accomplish justice." [Emphasis added]

Moore's continues at page 343:

> "It is important to note, however, that clause (6) contains two very important internal qualifications to its application: first, the motion must be based upon some reason other than those stated in clauses (1)-(5); and second, the other reason urged for relief must be such as to justify relief. [Emphasis added]
>
> In reference to the first qualification, the very cast of the Rule and the language of clause (6) indicate that this residual clause is dealing with matter not covered in the preceding five clauses. ..."

(3) The New York Analogue

In a footnote on Page 91, Moore's comments that the "New York courts probably have more extensive control over their judgments, without the necessity of resorting to the common law and equitable remedies, than the federal courts have even with such remedies".

Hence it may be helpful to take a peep into the applicable New York law.

While the New York courts have exercised a broad "inherent power, not confined rigidly by well defined rules, to set aside a verdict or vacate a judgment and order a new trial in the interests of justice" which is now said to be "codified" in or by Sections 4404 and 5015 of the Civil Practice Law and Rules (McCarthy v. Port of New York Authority, 21 A D 2d 125, 127, 1st Dept. (1964), the power until 1955 was confined to vacatur and to correcting clerical or inadvertant errors. Thus, in 1919, the New York Court of Appeals wrote:

> "The court had not the power to amend the judgment by awarding the costs of the action to the plaintiff. The rule has long been settled and inflexibly applied that the trial court has no revisory or appellate jurisdiction to correct by amendment error in substance affecting the judgment. It cannot, by amendment, change the judgment in matter of substance for error committed on the trial or in the decision, or limit the legal effect of it to meet some supposed equity subsequently called to its attention or subsequently arising. It cannot correct judicial errors either of commission or omission. Those errors are, under our system of procedure, to be corrected either by the vacating of the judgment or by an appeal [citing cases] ... Clerical errors or a mistake in the entry of the judgment or the omission of a right or relief to which a party is entitled as a matter of course may alone be corrected by the trial court through an amendment.

[citing cases]. A provision withholding or awarding costs is a substantive part of a judgment in an action in equity and cannot be amended. (Stevens v. Veriane, 2 Lans. 90; Smith v. Smith, 121 App.Div. 480; Foley v. Foley, 15 App.Div. 276)."

Herpe v. Herpe, 225 N.Y. 323, 327-8 (1919).

To the same effect, among numerous other cases, see

People v. Jackson, 307 N.Y. 271, 275 (1954);
Miltenberg & Samton, Inc. v. Falkingham, 273 App.Div. 631 (1948);
Matter of C of N.Y. 39 A D 2d 669 (1st Dept. 1972);
Baum v. Baum, 40 A D 2d 1000, 1001 (2d Dept. 1972).

In 1955, by amendment of then Section 549 of the New York Civil Practice Act and by the adoption of Rule of Civil Procedure 60-a, the courts were empowered, on hearing a motion, made within 15 days after the rendition of a decision, to "set aside the decision, take additional testimony, amend findings of fact and conclusions of law or make new findings and conclusions and render a new decision". That power, in somewhat modified form, is now set forth in CPLR 4404(b) and 4405. It is exercisable in cases "not triable of right by a jury" - rather than as specified in the 1955 amendments "in an action tried without a jury" - "upon the motion of any party"

made "within 15 days after decision" or on the court's "own initiative", presumably at any time before "argument or submission of an appeal from the final judgment". The "inherent power" to vacate a judgment, as distinguished from amending, is now the subject of CPLR 5015, entitled "Relief from judgment or Order"; it provides: "The court which rendered a judgment or order may relieve a party from it" on five specified rather narrow grounds.

CPLR 4404-4405 are comparable to FRCP 59; CPLR 5015 is comparable to FRCP 60, but is less comprehensive. What is important here is that New York practice never did and does not now permit the substantive alteration of final judgments, after a lapse of a short period of time, other than to vacate them.

(4) Precedents

Throughout Moore's extensive discussion of Rule 60(b) and the antecedent law, the power preserved or granted by that Rule is continually referred to as a power to grant "relief from" final judgments. Nowhere in the text is there a suggestion that power to "relieve from" includes or comprehends power to add

to, to increase, to expand, to enhance. All of the numerous pre-Rule and post-Rule cases cited in Moore's concerned relieving from or relaxing judgments and not with broadening or extending or expanding them. In discussing the equitable power in respect to executory or continuing injunctions, some of the cases spoke of it as a power to modify; however, in every instance the cases dealt with applications for eliminations or terminations and not the converse (e.g., United States v. Swift & Co., 286 U.S. 106 (1932); System Federation v. Wright, 364 U.S. 642 (1961); Stewart Dye Casting Corp. v. National Labor Relations Board, 129 F 2d 481 (7th Cir. 1942).

To the foregoing there is one exception, if it be an exception - the only one that has come to the attention of counsel. That one is Scott v. Young, 307 F.Supp. 1005 (E.D.Va. 1969), aff'd 421 F 2d 143 (4th Cir. 1970), cert. denied 398 U.S. 956, referred to in a footnote on page 344 of Moore's. In that case a consent decree entered in 1966 broadly and comprehensively enjoined the defendant "from denying the full and equal enjoyment of all the goods, services, facilities, privileges, advantages and

accommodations" of defendant's diversified establishment "for as long as there remained located on the ... premises the eating establishment" thereon. After that eating establishment was discontinued, the plaintiffs moved, in substance, for the elimination of the "so long as" clause. The District Court, in granting the motion, overruled the challenge to its jurisdiction on two grounds: (1) by its original order it "expressly retained jurisdiction"; (2) Rule 60(b)(6).

The Court of Appeals, 4th Circuit, without taking note of the jurisdiction issue, affirmed on the basis of the prohibitions in the Civil Rights Acts of 1964 and 1866 and the wide range of the enforcement decisions and judgments thereunder.

That determination, if justified, can be said that since the substance of what it did was <u>to eliminate</u> the "so long as" clause, it was a form of "relief from the operation of the judgment".

Whether or not so viewed, that case has no application to the substitution in this case of a far more drastic 13-page judgment for the original

3 1/2-page judgment.

II

THE POWER UNDER FRCP 60(b)(5) and (6) IS EXERCISABLE ONLY UPON EVIDENCE AND FINDINGS OF CHANGE OF CIRCUMSTANCES SINCE THE DATE OF THE JUDGMENT SO GRAVE AS TO JUSTIFY RELIEF FROM THE OPERATION OF THE JUDGMENT; HERE THERE ARE NO SUCH EVIDENCE OR FINDINGS.

(1). Of the six categories of "reasons" for which "the court may relieve a party ... from a final judgment ...", only the following can possibly apply here:

> "(5) ... it is no longer equitable that the judgment should have prospective application; or
>
> (6) any other reason justifying relief from the operation of the judgment."

In United States v. Swift & Co., supra, 286 U.S. 106 (1932), the court posed the question (at p. 115):

> "Power to modify existing, we are brought to the question whether enough has been shown to justify its exercise."

and reversed the District Court's partial relaxation of the continuing injunction precisely because it had not been established that the injunction had "turned through changing circumstances into an instrument of

wrong" (see pp. 114-115). At page 119, the court said:

> "There is need to keep in mind steadily the limits of inquiry proper to the case before us. We are not framing a decree. We are asking ourselves whether anything has happened that will justify us now in changing a decree. The injunction, whether right or wrong, is not subject to impeachment in its application to the conditions that existed at its making. We are not at liberty to reverse under the guise of readjusting. Life is never static, and the passing of a decade has brought changes to the grocery business as it has to every other. The inquiry for us is whether the changes are so important that dangers, once substantial, have become attenuated to a shadow. No doubt the defendants will be better off if the injunction is relaxed, but they are not suffering hardship so extreme and unexpected as to justify us in saying that they are the victims of oppression. Nothing less than a clear showing of grievous wrong evoked by new and unforeseen conditions should lead us to change what was decreed after years of litigation with the consent of all concerned."

Can the requirements for new impositions - if such be within the power of the court - be less drastic?

May changes be made even though nothing of serious consequence has happened to justify a change?

In System Federation v. Wright, 364 U.S. 642 (1961), the Supreme Court reversed the denial of a petition for relaxation because the proof did estab-

lish post-judgment developments which called for the elimination of one of the prohibitions. The court there said (at p. 647-8):

> " ... the court cannot be required to disregard significant changes in law or facts if it is 'satisfied that what it has been doing has been turned through changing circumstances into an instrument of wrong' United States v. Swift & Co., supra, at 114-115. A balance must thus be struck between the policies of res judicata and the right of the court to apply modified measures to changed circumstances".

In Schildhaus v. Moe, 335 F 2d 529 (2d Cir. 1964), the court reversed a vacatur of an injunction because, although in furtherance of justice, the vacatur was not justified by change of circumstances. Through Friendly, CJ, this court said (at p. 530):

> "The Director's motion misconceived the scope of the provision in F.R.Civ.Proc. 60(b) (5) authorizing relief when 'it is no longer equitable that the judgment should have prospective application.' The rule is not to be read without emphasis on the important words 'no longer'; assuming that the propriety of the injunction as issued has passed beyond debate, it refers to some change in conditions that makes continued enforcement inequitable. ... Here the facts of record as to the mailing of notice and the applicable rules of law were no different in the fall of 1963 than when the judge had made his initial determination a year earlier or when we affirmed it in July;

> the quoted clause in Rule 60(b) is 'no invitation to relitigation of matter adjudged by the original judgment'. 7 Moore, Federal Practice ¶ 60.26 [4], p. 288 (1955)."

In Stewart Dye Casing Corp. v. National Labor Relations Board, 129 F 2d 481, 7th Cir. 1942, the applicant sought "the elimination of that part of the decree which calls for an election by the employees before its recognition as the bargaining agent" (at p. 486). Quoting extensively from United States v. Swift & Co., 286 U.S. 106, the court denied the application because the evidence failed to establish that the provision "has become inapplicable by reason of changed conditions and circumstances arising subsequent to its entry".

(2). The 1972 judgment in this case was rendered after a very lengthy trial and several lengthy and detailed decisions. The present judgment purports to be "in accordance with the Findings of Fact and Conclusions of Law" in those prior decisions of December 18, 1971 and June 9, 1972 and the findings and conclusions, dated May 7, 1974 (128A). The latter comprises over 38 pages of legal cap (65A-103A). For the

most part it is a recital of pre-judgment events and determinations including extensive quotations from Judge Rosling's previous adjudications.

Of post-judgment occurrences, only the following appear: Defendant had evolved a "P/EmF" (intended to have all of the thermal capabilities of conventional diathermy) which it never marketed or tried to market. In the belief that the device would have those capabilities, defendant prepared small kits of wires and small parts to enable possessors of Diapulses to convert their devices, if they so desired, to P/EmF's, and in July-August, 1972 shipped several hundred of those kits to such possessors (65A-67A, 76A-85A). There is no claim and no finding that there were any shipments beyond those. Claiming that those shipments violated the judgment of July 18, 1972, the plaintiff, one year later, on August 1, 1973, instituted a criminal contempt proceeding (65A-66A). After 4 or 5 days of trial before Judge Dooling and a jury, the Judge dismissed the petition because "it would be legal error to submit the case to the jury since the jury could not, on the evidence, find beyond a reasonable doubt" that the complained of shipments

were "'articles of device known as DIAPULSE, or any similar articles of device ... in whole or in part, assembled or unassembled' within the required plain meaning of the permanent injunction" (93A-94A).

Judge Dooling, however, found dissatisfaction with the P/EmF and associated literature (79A-85A). He arrived at a similar conclusion in respect to another modality which defendant submitted to FDA for approval (92A-93A). There was no claim and there is no assertion or finding in the May 7, 1974 memorandum of any attempt whatsoever or any intention, after early August 1972 to make, without FDA approval, any interstate shipment of anything whatsoever, either devices, parts, equipment or literature. None was made other than a number of submissions to the FDA in compliance with the 1972 injunction.

What, in the foregoing recital, can justify the 1974 judgment in any respect in which it deviates from, or adds to, the 1972 judgment?

What, in that "Memorandum Incorporating Findings of Fact and Order" of May 7, 1974, can the plaintiff point to as justifying the new judgment on the basis of events since July 1972 - so serious or

poignant - to overcome the cardinal principle of res judicata and warrant the additional restraints and impositions?

III

THE RESERVATION OF JURISDICTION IN THE 1972 JUDGMENT DOES NOT DISPENSE WITH THE REQUIREMENT OF PROOF OF SUBSTANTIAL CHANGE. INDEED, SUCH A RESERVATION DOES NOT VEST POWER NOT OTHERWISE POSSESSED.

(1). In United States v. Swift & Co., supra, 286 U.S. 106, the following appears at pages 111-112:

> "The [original] decree closed with a provision whereby jurisdiction of the cause was retained for the purpose of taking such other action or adding at the foot such other relief 'as may become necessary or appropriate for the carrying out and enforcement' thereof, 'and for the purpose of entertaining at any time hereafter any application which the parties may make' with reference thereto."

Nevertheless, the Supreme Court held that no change lawfully could be made in the absence of "change in circumstances" sufficient "to justify" the changes which the district court had made. It said also:

> "If the reservation had been omitted, ... there still would be" the same power "by force of principles inherent in the jurisdiction of the chancery" (at p.119).

Thus it seems clear that whether or not there is an articulated reservation of "jurisdiction" and regardless

of its terminology, the power and the extent thereof are the same.

It follows that reservation of jurisdiction, per se, does not vest power not otherwise possessed.

Except as to jurisdiction over a person, it is a truism that consent cannot vest in a court a jurisdiction it does not possess by law (e.g., United States v. Mayer, 235 U.S. 55, 1914). Surely, a court cannot by its own edict give itself or extend a jurisdiction or a power it would not otherwise possess.

(2). Moreover, the reservation in the July 1972 judgment was far more restrictive than the reservation quoted above. It reads (64A):

> "The Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate."

Thus by its own terms it bars changes other than such "as may hereafter appear necessary or appropriate". And the changes wrought by the judgment of July 1974 have not been shown "necessary or appropriate" within

the requirements of United States v. Swift & Co., and Schildhaus v. Moe, quoted at pages 33-36 supra.

IV

THE 1972 JUDGMENT HAVING BEEN AFFIRMED BY THIS COURT, IT, ON THAT GROUND, IS DOUBTFUL THAT THE DISTRICT COURT HAD JURISDICTION TO CHANGE THE JUDGMENT WITHOUT LEAVE OF THIS COURT.

Undoubtedly, it is the general rule that, upon affirmance, a District Court's judgment becomes a judgment of the Court of Appeals, over which the District Court has no power other than to enforce it as affirmed (7 Moore's Federal Practice, 2d Ed. pp. 425-9 and cases cited therein).

However, since the affirmed judgment in this case contained a reservation by the District Court of jurisdiction over it, it may be argued that the affirmance was subject to that reservation. But that reservation, we have seen, is ineffective to reserve a power which otherwise is unpossessed. There is a further consideration: Did this Court, by its affirmance, intend to cede part of its exclusive jurisdiction and, if it did, was that within this Court's power?

V

A NUMBER OF THE PROVISIONS IN THE 1974 JUDGMENT ARE INCONSISTENT WITH THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND ARE CONTRARY TO LAW.

(1). The 1974 judgment (see supra pp. 5-7) prohibits defendant from marketing interstate conventional diathermy devices without FDA pre-clearance of labeling (126A-135A).

Such clearance is not provided for by statute or regulation.

The basis of the 1972 injunction is that defendant had marketed athermal or non-thermal Diapulses with therapeutic claims that were are are standard for conventional diathermy (62A-63A, 68A-72A, 86A-94A, 98A); and the injunction related solely to such device (cf.61A-63A with 98A and 126A-127A). It does not follow that therefore the defendant should be prohibited from marketing devices that have all of the thermal capabilities of conventional diathermy. In an earlier decision, Judge Dooling had ruled, on January 29, 1974 (104A):

> " ... nothing on earth, of course, could prevent defendants from making and marketing a conventional diathermy machine ..."

(2). The 1974 judgment (see p. 7 supra) defines "held for sale" in Section 301(k) of the Food, Drug and Cosmetic Act (hereinafter referred to as the Act) as including possession by a licensed practitioner for use on his patients and not for sale. Since defendant is not a therapist and has no patients, that dictum has no application to defendant. Its effect can be only to prejudice the rights of persons who are not before the court - practitioners who may resist or desire to resist seizure on the ground that instruments which they use in the course of their practice are not "held for sale" and thus are not within the "seizure" jurisdiction of the court.

By what principle of equity should they be foreclosed in absentia?

In United States v. Sullivan, 332 U.S. 689 (1947), a drug which was required to be marketed with prescribed labeling containing danger warnings was sold by a pharmacist without such labeling. Clearly, those drugs were "held for sale". Yet, there was a serious question whether they were "held for sale" within the constitutional meaning of the statute. The

Supreme Court held that it did because "the Act as a whole was designed primarily to protect consumers from dangerous products" and the drug in question was potentially dangerous. It did not follow, the court said, that the same is true in relation "to food, cosmetics and the like" and would apply to "retail grocers and beauty parlor operators". In the case of therapists using Diapulse on their patients, it is fanciful to assert that thereby the therapist sells the device or is holding it for sale. A sale is a transfer of title. No such transfer is effected or contemplated. Nor is there ever a transfer of possession or in contemplation.

(3). There is no provision in the Act for the recall of devices.

Moreover, it is critically pertinent to inquire what changes took place after July 1972 to warrant the insertion in 1974 of provisions requiring the defendant to "cause" all present owners and holders of Diapulses which had been sold during preceding decades - all prior to July 18, 1972 - to return them to the defendant? The answer is there is no

claim, evidence or finding of such changes.

The recall, conversion or destruction provisions in sections II(E)(2), IV(D) (1), (2), (3), at 133A-135A - see supra pp. 7-9) impose upon the defendant a tremendous and very costly burden in respect to perhaps 4,000 machines sold years ago. What principle of law or equity authorizes that? And we respectfully repeat: If such provisions were not deemed necessary or appropriate or proper in 1972, what has occurred since to warrant them in 1974?

(4). The sweeping provisions for inspection of the premises, files and documents, with right to copy (section V(B) at 135A-136A - see pp. 9-10 supra) transcend the Inspection provisions of the Act - (see Section 374 reproduced at pages 48-50 infra). As to "devices" as distinguished from food, drugs or cosmetics, the statute provides that "For purposes of enforcement of [the Act], officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse or estab-

lishment in which ... devices ... are manufactured, processed, packed or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such ... devices ... in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein". [Emphasis added]

Under that section, inspection of records, files, papers, processes, controls and facilities, are authorized only in places where drugs are manufactured, and excluded from inspection are financial, sales, pricing and personnel data. The statute requires also "a separate notice ... for each such inspection" and, in certain cases, the delivery by the inspector before leaving the premises of a report of his findings.

Since none of the defendant's activities since August or September 1972 have been "for introduction into interstate commerce" of anything, no inspection is warranted under Section 374, and under no circum-

stances, under the provisions of the statute, are defendant's files, records and papers open for compulsory inspection.

Moreover, if provision for inspection was not deemed necessary or appropriate in 1972, what reason is there for such provision in 1974?

(5). Since due notice of the 1972 judgment was given in accordance with its terms to all known possessors of Diapulses and since defendant since then has not sold or shipped any Diapulses in interstate commerce, what warrant is there for requiring the mailing to all such persons of a copy of the new judgment?

CONCLUSION

THE 1974 JUDGMENT SHOULD BE REVERSED AND VACATED, WITH COSTS.

Respectfully submitted,

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August 27, 1974.

inspectors of Federal Food and Drug Administration, under this section, providing that evidence obtained thereunder from person failing to permit access to and copying of records, showing movement in interstate commerce of foods or drugs received or held by him, on government officer's or employee's request, shall not be used in criminal prosecution of such person, where sections 372 and 374 of this title authorize such type of inspection, investigation and collection of samples and defendants voluntarily supplied information sought by inspectors. Id.

This section providing that records of interstate shipments of food, drugs, etc., shall be subject to inspection by government agent but that evidence thus obtained shall not be used in criminal prosecution of person from whom obtained was not applicable to suppress evidence voluntarily given government agent who made inspection pursuant to section 374 of this title authorizing factory inspection. U. S. v. Scientific Aids Co., D.C.N.J.1954, 117 F.Supp. 588.

In prosecution for having introduced misbranded drugs into interstate commerce and for misbranding drugs held and intended for shipment in interstate commerce wherein defendants moved to suppress evidence allegedly acquired by government agent in violation of defendants' constitutional and statutory rights under this section, evidence showed that defendants had voluntarily surrendered such evidence and had voluntarily made pertinent records available to government and had acquiesced in agent's examination of such records. Id.

§ 374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions

subject to this chapter), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (j) or section 357(d) or (g) of this title, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness." The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Written report to owner; copy to Secretary

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been ren-

dered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Receipt for samples taken

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Analysis of samples furnished owner

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

June 25, 1938, c. 675, § 704, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, c. 350, § 1, 67 Stat. 476; Oct. 10, 1962, Pub.L. 87-781, Title II, § 201(a), (b), 76 Stat. 792.

Historical Note

1962 Amendment. Subsec. (a). Pub. L. 87-781, § 201(a), extended the inspection, where prescription drugs are manufactured, processed, packed, or held, to all things bearing on whether adulterated or misbranded drugs, or any which may not be manufactured, introduced in interstate commerce, or sold or offered for sale under any provision of this chapter, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this chapter, but excluded from such inspection, data concerning finance, sales, other than shipment, pricing, personnel, other than relating to new drugs subject to reporting, provided that the provisions of the second sentence of this subsection shall be inapplicable to pharmacies, practitioners and other persons enumerated in pars. (1)-(4), and eliminated "are held" preceding "after such introduction."

Subsec. (b). Pub.L. 87-781, § 201(b), inserted "consulting laboratory" following "warehouse."

1953 Amendment. Act Aug. 7, 1953 designated existing provisions as subsec. (a) and amended them by substituting provisions permitting entry and inspection upon presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge for provisions which authorized entry and inspection only after making a request and obtaining permission from the owner, operator, or custodian, and inserting provisions requiring a separate written notice for each inspection but not for each entry made during the period covered by the inspection, and directing that the inspection shall be conducted within reasonable limits, in a reasonable manner and completed with reasonable promptness, and added subsecs. (b)-(d).

Effective Date of 1962 Amendment. Amendment of section by Pub.L. 87-781 effective Oct. 10, 1962, see section 203 of Pub.L. 87-781, set out as a note under section 332 of this title.

Effective Date. Section effective twelve months after June 25, 1938, see section